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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,711	11/14/2001	Avi J. Ashkenazi	P2730P1C2	4031

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. 09/990,711	Applicant(s) ASHKENAZI ET AL.
Examiner Elizabeth C. Kemmerer, Ph.D.	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 119-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 119-123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The amendment and response received 27 October 2003 has been entered in full. Claims 1-118 and 124 are canceled. Claims 119-123 are under examination.

The declarations of Drs. Goddard and Ashkenazi filed with the amendment and response under 37 CFR 1.132 have been received and entered into the record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

The objection to the specification for containing embedded hyperlinks as set forth at p. 2 of the previous Office Action (Paper No. 7, 30 July 2003) is *withdrawn* in view of the amendment received 27 October 2003.

The rejection of claims 119-124 under 35 U.S.C. § 112, second paragraph, as set forth at p. 6 of the previous Office Action (Paper No. 7, 30 July 2003) is *withdrawn* in view of the canceled and amended claims submitted in the amendment received 27 October 2003.

### ***35 U.S.C. §§ 101 and 112, First Paragraph***

Claims 119-124 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a credible, specific and substantial asserted utility or a well established utility.

Claims 119-124 are also rejected under 35 U.S.C. § 112, first paragraph.

Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would clearly not know how to use the claimed invention.

The basis for these rejections is set forth at pp. 2-6 of the previous Office Action (Paper No. 7, 30 July 2003).

Applicant's arguments submitted in the response received 27 October 2003 have been fully considered but are not found to be persuasive for the following reasons. The Goddard and Ashkenazi declarations under 37 CFR 1.132 filed 27 October 2003 are insufficient to overcome the rejection of claims 119-124 based upon 35 U.S.C. §§ 191 and 112, first paragraph, as set forth in the last Office action for the following reasons.

Applicant discusses the gene amplification assay, and provides two declarations under 37 CFR 1.132 (the Goddard and Ashkenazi declarations) to address the concerns regarding the assay raised in the previous Office Action. These arguments and declarations, including publications using the same assay, have been very helpful in addressing the questions raised in the previous Office Action. It is now conceded that the gene amplification assay provides a patentable utility for the PRO341 nucleic acid. However, the instant application has claims directed to PRO341 antibodies.

Applicant argues that the utility of the PRO341 nucleic acid carries over to the protein and antibody claims. Specifically, Applicant argues that there is an assumption of utility unless a reason for one skilled in the art to question the objective truth of the statement of utility or its scope can be established. Applicant cites case law in support

of this assertion. Applicant urges that a *prima facie* case of lack of utility has not been established. Applicant criticizes the examiner's reliance on Pennica et al. (of record), stating that the examiner has not established whether or not the lack of correlation between gene copy number and protein levels for WISP family members is an exception to the rule, or is the rule. Applicant asserts that the working hypothesis among those skilled in the art is that, if a gene is amplified in cancer, the encoded protein is likely to be expressed at an elevated level. This has been carefully considered but is not found to be persuasive. No evidence has been submitted that it is the norm rather than the exception that protein levels are increased when gene amplification occurs in cancer. Indeed, given the disclosure in art, such as Pennica et al., that there is not always such a correlation, the skilled artisan would not assume it is so, but would perform the experiment to verify it. See also Konopka (Proc. Natl. Acad. Sci. (1986) 83:4049-4052), who state that "Protein expression is not related to amplification of the *abl* gene but to variation in the level of *bcr-abl* mRNA produced from a single Ph1 template" (see abstract). Finally, the art even shows that protein levels are also not predicted by transcript levels. See Haynes et al. (1998, Electrophoresis 19:1862-1871), who studied more than 80 proteins relatively homogeneous in half-life and expression level, and found no strong correlation between protein and transcript level. For some genes, equivalent mRNA levels translated into protein abundances which varied more than 50-fold. Haynes et al. concluded that the protein levels cannot be accurately predicted from the level of the corresponding mRNA transcript (p. 1863,

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second paragraph, and Figure 1). Therefore, the art indicates that it is not the norm that gene amplification, or even increased transcription, results in increased protein levels.

Finally, Applicant refers to the Ashkenazi declaration which asserts that if the protein levels do not increase as a result of gene amplification, it is also useful because it can serve to better diagnose the cancer. This has been fully considered but is not found to be sufficient to withdraw the rejection, since there is no indication that the PRO341 protein levels increase or stay the same. Further research would be needed to determine PRO341 protein levels in cancers showing gene amplification of PRO341 gene. Therefore, the asserted utility is not substantial, as the real-world use has not been established. Thus, the proposed use of the PRO341 proteins (and by extension the antibodies as claimed in this application) are simply starting points for further research and investigation into potential practical uses of the proteins and antibodies.

See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Therefore, the rejections under 35 U.S.C. §§ 101 and 112, first paragraph, are maintained.

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**Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ECK

ELIZABETH KEMMERER  
PRIMARY EXAMINER